



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-1997]

Food and Drug Administration Oversight of Food Covered by Systems Recognition Arrangements; Guidance for Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for FDA staff entitled “FDA Oversight of Food Covered by Systems Recognition Arrangements.” This guidance provides recommendations related to FDA’s regulatory oversight activities for food covered by a Systems Recognition Arrangement (SRA) and imported from countries whose food safety systems FDA has recognized in SRAs.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in

the body of your comments, that information will be posted on

<https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2019-D-1997 for “FDA Oversight of Food Covered by Systems Recognition Arrangements; Guidance for FDA Staff.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit

both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)). Submit written requests for a single hard copy of the guidance entitled “FDA Oversight of Food Covered by Systems Recognition Arrangements” to the Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Building, Rm. 4148, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Marla Hallacy, Office of Regulatory Affairs, Division of Operational Policy, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-6674.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for FDA staff entitled “FDA Oversight of Food Covered by Systems Recognition Arrangements; Guidance for FDA Staff.” The guidance is part of FDA’s larger effort to take a risk-based approach to food safety to include ensuring the safety of imported food, consistent with the FDA Food Safety Modernization Act. The guidance covers FDA’s regulatory oversight activities for food covered by SRAs between FDA and its foreign regulatory counterparts. Currently, FDA has signed SRAs with food safety agencies in Australia, Canada, and New Zealand.

On July 12, 2021, FDA made available the draft guidance entitled “FDA Oversight of Food Products Covered by Systems Recognition Arrangements; Draft Guidance for Food and Drug Administration Staff” in the *Federal Register* (86 FR 36559). The comment period closed on September 10, 2021. FDA received no comments on the draft guidance. The Agency made minor editorial changes to the guidance to improve clarity. The guidance announced in this notice finalizes the draft guidance.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the topic of SRA implementation. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information regarding the Foreign Supplier Verification Program have been approved under OMB control number 0910-0752, the collections of information regarding the Hazard Analysis and Critical Control Point Procedures

for the Safe and Sanitary Processing and Importing of Juice have been approved under OMB control number 0910-0466, and the collections of information regarding the Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products have been approved under OMB control number 0910-0354.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> or <https://www.regulations.gov>.

Dated: June 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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